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Acceptability and Feasibility of Examining Physical Activity in Young Children with Type 1 Diabetes

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Abstract

Physical activity (PA) is important but may be difficult to evaluate in young children (YC) with type 1 diabetes (T1D) due to parents' fears of hypoglycemia, difficulties engaging YC in PA, and use of assessment devices. This study aimed to explore the acceptability and feasibility of an in-lab exercise session for YC with T1D. 10 YC aged 3-7 years with T1D participated in a 20 minute exercise session while wearing blinded continuous glucose monitors and accelerometers. High acceptability was found for participation in the exercise session; high feasibility and acceptability were reported for the assessments. Though the majority of children completed the session, it did not produce moderate-to-vigorous physical activity. YC were found to spend most of their day sedentary, and had frequent blood glucose (BG) excursions. Findings support the feasibility of conducting a more extensive examination of the relationship among BG levels and PA in YC with T1D.

Keywords

type 1 diabetes; young child; exercise; physical activity; research methods

The incidence of type 1 diabetes (T1D) is increasing, with the most rapid growth in young children (< 5 years; Dabelea et al., 2014). The American Diabetes Association recommends a target hemoglobin A1c of less than 7.5% for youth (American Diabetes Association, 2017), yet most have difficulty meeting this goal (Wood et al., 2013) and adequate diabetes management likely requires even more vigilance for parents of young children (Streisand &

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Monaghan, 2014). Improvements in A1c are associated with regular PA (Schwab et al., 2016), though this relationship has been less clear in younger children (Leclair, De Kerdanet, Riddell, & Heyman, 2013). As parents strive to maintain within range BG levels (90-150 mg/DL recent recommendations by the American Diabetes Association for all youth under age 19²), they may consider PA as one important tool to help curb high BG levels. Despite well-known long-term benefits of PA, the potential for acute effects of BG levels decreasing to an unsafe level during PA warrants further study (Leclair et al., 2013). Young children are at particularly high risk of acute glycemic excursions given their difficulty detecting and communicating hypoglycemia symptoms, which has been associated with a threefold increase in mortality (Franchini, 2016). In experimental studies, youth with T1D who engaged in afternoon PA have been found to have a 38-80% higher risk of nocturnal hypoglycemia (Bachmann, Hess, Martin-Diener, Denhaerynck, & Zumsteg, 2016; Metcalf et al., 2014) and close BG monitoring for 72 hours after PA has been recommended (McMahon et al., 2007). However, meta-analyses of PA interventions in youth with T1D report few instances hypoglycemia (Wu, Thompson, Aroian, Mcquaid, & Deatrck, 2016) and studies with adults suggest minor increases in hypoglycemia can be addressed with insulin adjustments prior to the start of PA (Chimen et al., 2012).

There are several limitations to the existing literature on PA in children with T1D. Many studies have had a primary focus on adolescents, used non-objective measurements of PA, or failed to capture the time-sensitive impacts of PA on BG (Tully, Aronow, Mackey, & Streisand, 2016). More research is needed to determine if models of BG variability built on adolescent and adults apply to YC, whose PA engagement often occurs throughout the day in 'bursts' rather than in discrete periods of time (Ruiz, Tracy, Sommer, & Barkin, 2013). Further, little is known about the best method to measure the activity patterns of young children with T1D and the immediate impact of YC's PA levels on their BG regulation. Last, as parents may avoid intensive PA for their child due to their own hypoglycemia fears, (Jabbour, Henderson, & Mathieu, 2016) the feasibility of conducting an experimental exercise session in young children with T1D is unknown.

The primary aim of this study was to determine the feasibility measuring PA of young children with T1D in a lab-setting and home. Secondary aims are to conduct preliminary explorations of the relationship between BG and PA, with the goal of hypothesis generation regarding future larger investigations as well as intervention targets for improving glycemic control. The exercise session and a naturalistic observational period using objective measures of BG and PA are described.

Method

Ten children (M age= 5.88 years, 80% female, M A1c = 7.32% $\pm$ 0.50) with T1D for at least one year (M duration = 2.78 $\pm$ 1.55 years) participated. Children were Caucasian (60%), African American (20%), and Hispanic/Latino (20%). Parents were all married (90% mothers) and predominantly had a four-year college degree (90%). Eight children used a basal-bolus regimen; two were on fixed dose conventional insulin regimen. Parents checked their children's BG levels an average of 6.70 $\pm$ 2.29 times/day by BG monitoring. The study

was conducted at a pediatric academic medical center in the mid-Atlantic and all procedures were approved by the Institutional Review Board.

The child and parent attended a study visit at the clinical research center. After arrival, the research nurse measured height/weight and inserted a blinded continuous glucose monitor (CGM; iPro, Medtronic, Northridge, CA) on the children, who were also fit with wrist accelerometers. Evidence supports wrist placement of the accelerometer used in this study with young children (Johansson, Ekelund, Nero, Marcus, & Hagströmer, 2015). Parents were instructed to calibrate four times a day with BG meter readings. Following CGM insertion, children were engaged in sedentary behaviors while parents completed questionnaires, and then the family ate lunch in the hospital cafeteria. Two hours after lunch, if the child's BG level was between 100-200mg/dL, the child participated in 20 minutes of a developmentally appropriate PA of their choice: a dancing game (Just Dance for Kids, by Nintendo Wii) or a preschool exercycle (Fisher Price Smart Cycle). Games were selected for appeal to children this age, and prior use in PA programs (Gao, Chen, Pasco, & Pope, 2015). Children were monitored for any signs of hypoglycemia via CGM as well as visually during, and for one hour following, the exercise session. If needed, children with lower BG level (< 100 mg/dl) were given a 15 gram carbohydrate snack and BG levels monitored until in an acceptable range (> 100 mg/dl) before being discharged. A summary of the CGM findings was offered to families at the conclusion of the study and given to the physician, with permission.

Accelerometers were used to measure accelerations or gyrations, and provide information as to the initiation, duration, and magnitude of movement during daytime activities (Ambulatory Monitoring Inc., Ardsley, NY). Accelerometer counts were recorded at 1-minute intervals throughout the 5 day period. Time-stamped activity data were categorized as MVPA if energy expenditure was >0.04 kcal/kg/min and vigorous-intensity PA if activity energy expenditure was >0.10 kcal/kg/min (Maslow & Colabianchi, 2011). This corresponded to accelerations as follows: sedentary < 100 counts/minute; light > 100 counts/minute; moderate 1001-2296 counts/minute; and vigorous > 4012 counts/minute (Evenson, Catellier, Gill, Ondrak, & McMurray, 2008). Participants continued CGM and PA monitoring for a total of five days (including one weekend day) following discharge and asked to engage in their usual daily routines.

Participants completed 24-hour recall interviews by phone daily for five days following the physical activity session with trained research staff reporting on the child's diabetes management, PA, and diet while in the home setting. The timing of PA by parent report was coded using Mill's (1974) ordinal method. A time period of < 10 minutes was counted as a period of PA; 7:00am-12:00pm rated as morning, 12:01-5:00pm as afternoon, and 5:01-10:00pm as evening to rate each participant's PA as majority morning, majority afternoon/evening, or mixed morning and afternoon/evening.

Parents completed a version of the Physical Activity Questionnaire (PAQ; Crocker, Bailey, Faulkner, Kowalski, & McGarth, 1997) modified for use with young children to assess MVPAs. Each of the 10 items is rated on a five-point Likert scale where responses are given on a 1 (*very satisfied*) to 5 (*very dissatisfied*) range. The first item was modified to include

developmentally-appropriate options, such as skipping and playing tag ($\alpha=0.73$). The PAQ has demonstrated adequate test-retest reliability²⁷. A subsample (40%) of parents participated in qualitative interviews on feasibility and satisfaction.

Results

Feasibility and Acceptability

All 10 children had successful placement of the CGM equipment (> 1 placement attempt was required for 3 of the 10 children). Three of the children changed tasks during the PA session (i.e., switched from Nintendo dance to exercycle). Nine participants selected the dance exercise game, and six used the exercycle. One participant played both games and then completed jumping jacks, running/chasing, and stair climbing with staff to reach the 20-minute target. One participant had equipment malfunction and accelerometer data were not available for the exercise period. The remaining sample ($n = 9$) had a mean acceleration in the Light activity category (mean accelerations/minute of 1476.82 ± 703.94 ; range 599.65-2664.05), with only 2 participants demonstrating Moderate activity and none reaching Vigorous (Evenson et al., 2008). To compare the exercise session with children's normal activity, accelerometer data for the observation period was explored at times when parents reported children were engaged in more than 20 minutes of PA. Accelerometer data was defined as valid and usable with a minimum of 1,500 daily steps. Activities included gymnastics and playing tag (M accelerations/minute = 1897.54 ± 626.51 , indicating Light activity). No significant difference was observed between children's activity levels during the exercise session and times when parents reported engagement in vigorous activity ($t(8) = 1.78$, $p = 0.78$, suggesting that the exercise game mimicked natural engagement in PA.

For the observational period, CGM data were considered usable if the majority (>50%) of the day consisted of uninterrupted CGM readings. There was 72% usable CGM data and 90% usable accelerometer data. All children kept CGM on during the exercise session and most ($n=7$) wore it during the entire five day observation period; the remaining returned at least three days of uninterrupted CGM data. One accelerometer malfunctioned; data were available for the exercise session and observation period for nine of the children. At least three days of 24-hour recall data were available for the full sample. When asked in feedback interviews, parents reported satisfaction with study participation with one saying it was “a useful and positive experience” and no parents reported concerns regarding the exercise session.

Health Behaviors Description

Children spent a majority of their days in BG excursions outside of the range set forth by the ADA (Table 1). BG varied throughout the day with the larger excursions occurring after breakfast. There were no incidents of hypoglycemia for any of the children during the exercise session nor during the hour immediately following. There was no significant difference between duration of time spent below 90 mg/dl on the day of the exercise session (mean = $5.10\% \pm 7.34$) compared to day 3 of the study (mean = $10.80\% \pm 11.38$), ($t(9) = -1.11$, $p = 0.30$). Nocturnal hypoglycemia was coded for BG values 8:00pm-6:00am. There was no significant difference in nocturnal BG means for the night following the exercise session (M

= 194.53±52.15) in comparison to the third night of the study ($M = 177.00 \pm 87.96$), $t(9) = 0.67$, $p = .67$.

From parent report on the PAQ, seven participants were categorized as majority sedentary, two as light PA, and one as moderate PA. Participants were significantly less active than samples of children without T1D, $t(6317) = 5.31$, $p < 0.0001$ (mean MVPA = 19.51 min/day ±24.67; mean MVPA = 42.90 min/day±13.90 as reported in a meta-analysis representing 6,309 preschoolers; Bornstein, Beets, Byun, & McIver, 2011). Most (7/10) engaged in activity in the afternoon-evening time; the remainder (3/10) had activity in the morning and afternoon. Parents reported universally high satisfaction ($M = 1.70$, range 1-2) with their child's current level of PA on the PAQ, which showed children were majority sedentary ($M = 2.46 \pm 0.61$). There was no association between MVPA and time spent in low excursions ($r = 0.27$, $p = 0.45$) as measured by accelerometer. Participants who engaged in PA during the morning as well as afternoon trended toward less time in overall BG excursions ($p = 0.55$, $p = 0.06$) as compared to participants with primarily afternoon-evening time.

Conclusion

This study was a pilot to determine the feasibility of using an in-lab exercise session with multiple assessment devices in young children with T1D to explore the relationship among PA and BG variability. The methods used have implications for the study of PA in young children across health populations. The study assessments, including use of wearable technologies and naturalistic observation, were acceptable and feasible to parents and children. There were challenges in achieving MVPA during the 20 minute exercise session. In addition, even the children who had adequate glycemic control as measured by A1c spent a significant portion of their day outside of the recommended BG range. Second, young children are more sedentary than parents perceive. This is problematic, as regular PA is part of overall diabetes management, yet parents may believe their children are already engaging in enough PA.

While acceptability of participating in the exercise session was high, children's PA level during the session did not reach a high intensity level. Several factors that should be explored in future research may help understand why this occurred. The activities selected might not have sustained interest at the level required to achieve a higher PA intensity. Further exploration of the relationship of PA and BG is recommended in children using a higher intensity exercise session, such as developmentally modified treadmill tests involving altering grade and speed like the Bruce protocol typically used to measure maximal oxygen uptake (Singh, Rhodes, & Gauvreau, 2008; Treiber et al., 1989). Alternately, children might be more likely to stay engaged at a higher intensity if the target PA duration was shortened (e.g., 5 minutes), which might be more similar to the daily PA experiences of YC. It is also possible that children in this age range may benefit from increased social facilitation to stay engaged in a time-limited exercise task, so future designs could explore engaging parents or group exercise sessions as a method to achieve MVPA. Future research should also include measures of parental fear of hypoglycemia in relation to PA. Results from an in-lab exercise session cannot be interpreted as directly informing free-standing PA, as for preschoolers the majority of PA occurs in unstructured playtime (e.g., running, jumping; Tucker, 2008). There

may be targets for future interventions in educating parents about the importance of PA, feedback on amounts of PA their child receives, and the actual risks of hypoglycemia as related to PA. In addition, this was a small sample and overinterpretation of the results should be avoided. There is a need for additional pilot testing of various exercise sessions to determine the best model to yield the desired PA intensity levels.

These limitations aside, findings indicate that the activity of young children with T1D may be different than in older children, adolescents, and adults, and it's acceptable to conduct a hospital-based exercise session using objective data using multiple wearable. In particular, it is necessary to identify the best methods for testing young children's exercise and BG variability in youth with T1D. Only then can answers be found about how discrete periods of MVPA impact BG variability in these young children populations, and if relationships mimic findings in adults (Terada et al., 2013). The longer term goal of such research is to develop clinical guidelines for families of young children with T1D to help them promote routine and safe PA which will ultimately promote positive child health outcomes.

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Table 1
Group Glycemic Variability (N=10)

Blood glucose (BG) Measure	Mean (SD)	Range
BG level from meter	186.22 (41.87)	120–261
BG level from CGM sensor	193.79 (57.07)	65–275
Pre-Breakfast BG	181.97 (45.80)	96.50-251.52
Post-Breakfast BG	247.23 (86.07)	155-376.75
Pre-Lunch BG	190.66 (70.02)	86.50-327.80
Post-Lunch BG	189.31 (34.20)	146.00-235.40
Pre-Dinner BG	187.60 (74.11)	100.50-309.67
Post-Dinner BG	196.75 (54.58)	126.00-293.67
Overnight BG	184.67 (41.26)	64.00-224.54
% time spent in range (90-150 mg/dL) - CGM	27.12 (11.84)	7.20–45.60
% time spent <90 mg/dL (hypoglycemia) - CGM	10.94 (7.95)	0–24.20
% time spent >150 mg/dL (hyperglycemia) - CGM	61.94 (17.59)	30.20–90.20